

## **REMARKS**

### **I. Preliminary Remarks**

Claims 20-23, 25, and 28-31 are under consideration and are rejected. Claims 12-19, and 32-75 are withdrawn with traverse and without prejudice as being drawn to non-elected invention. Claims 1-11, 24, 26-27, and 76-83 are canceled. In this response, Applicant addresses each of the rejections raised by the Examiner. Support for the amendments to the claims is found throughout the specification. The amendments do not include new matter. Reconsideration and withdrawal of the rejections are solicited for the reasons set out below. Applicant respectfully submits that the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

This Response is timely filed without the need for an extension of time. The USPTO is given authorization to charge any fees necessary with this submission, and to credit any over payment of fees, to Applicants' Deposit Account No. 16-1445.

### **II. Patentability Arguments**

#### **A. The Obviousness Rejection of Claims 20-23, 25, and 28-31 under 35 U.S.C.**

##### **§103(a) May Be Properly Withdrawn.**

As stated in the MPEP (§2141), to support an obviousness rejection, four basic criteria must be met. These are (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. Clearly for prior art to render an invention obvious, it must render obvious the whole invention and not merely some part of the invention (*In re Antonie* 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1997)). The prior art must also be considered as a whole including parts that teach away from Applicant's invention. Applicant respectfully submits that these criteria are not met in the Examiner's rejections.

The Examiner rejected claims 20-23, 25, and 28-31 under 35 U.S.C. 103(a) as being unpatentable over Bowland, et al., (Canadian Veterinary Journal, Jan 2000, Vol. 41, No. 1, pages 33-48) and Fulton, et al., (Vaccine, 15 September 2000, Vol. 19, No. 2-3, pages 264-

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274) in view of Lidgate, et al. (Pharmaceutical Research, 1989, Vol. 6, No. 9, pages 748-752) and Brake, et al., (US Patent No. 6,787,146, Sept 2004; publication US2002/0058046, 16 May 2002). Applicants respectfully traverse this rejection.

As stated by the Examiner, Bowland does not teach a vaccine that is microfluidized and does not teach a vaccine composition comprising BVDV types 1 and 2 in the same vaccine. In addition, Bowland does not teach a vaccine composition with an adjuvant comprising Quil A, lecithin and oil blend and cholesterol or indicate if the BVDV strains are cytopathic or noncytopathic. Thus, Bowland do not teach or suggest Applicants' invention.

Fulton describes vaccines comprising BVDV types 1 and 2 but makes no mention of an adjuvant or of microfluidized compositions. Thus, Fulton does not teach or suggest Applicants' invention.

Brake describes a parasite vaccine while Applicant's invention comprises viral and bacterial vaccines. Brake describes a homogenate vaccine while Applicant's invention comprises whole virus or whole bacteria vaccines. Thus, while Brake demonstrates that the adjuvant works for a homogenate parasite vaccine, they do not demonstrate that the adjuvant works in a whole cell viral or bacterial vaccine. Brake also does not mention microfluidized compositions. Thus, Brake does not teach or suggest Applicants' invention.

Lidgate did not test vaccines for their ability to trigger an immunoprotective response, but instead for only their ability to induce an immunogenic response. However, *In re Wright* (999 F.2d 1557, 1561, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)) teaches that "A vaccine must by definition trigger an immunoprotective response in the host vaccinated; mere antigenic response is not enough." There is no description or enablement in the cited reference of a vaccine triggering an immunoprotective response in the host. The claims in the instant application are drawn to vaccine compositions, and Applicants have demonstrated an immunoprotective response. In addition Lidgate does not teach an adjuvant comprising Quil A, lecithin and oil blend, and cholesterol.

Applicants respectfully submit that none of the references cited by the Examiner suggest Applicant's invention. In addition, Applicant respectfully submits that the MPEP (2143.01) teaches that merely because the references can be combined does not render the combination obvious. The prior art must suggest the desirability of making the combination.

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*In re Fritch* (CAFC 1992) 972 F2d 1260, 23 PQ2d 1780. Before one determines that the prior art teaches one of ordinary skill in the art to make the changes necessary for the present invention, one must first determine that the prior art suggests that the references be combined. *Monarch Knitting Mach. Corp. v. Sulzer Morat GmbH* (CAFC 1989), 139 F3d 877, 45 PQ2d 1977. However, there is no indication in any of the references that would suggest that the references be combined, and thus there can be no reasonable expectation that such a combination would be successful. The Examiner is using hindsight to select bits and pieces of the prior art in an attempt to create a combination rejection, which is an inappropriate process. Applicants respectfully submit that this rejection under 35 U.S.C. 103(a) may be properly withdrawn. Applicants respectfully request withdrawal of this rejection.

Accordingly, it is respectfully submitted that the vaccine compositions, as presently claimed, are not rendered obvious by Bowland et al. and Fulton et al. in view of Lidgate et al. and Brake et al. Thus, based on the remarks presented herein, when combined with the arguments provided in the responses to the prior office actions in this application, the rejection of claims 20-23, 25, 28-31 under 35 U.S.C. 103(a) is overcome. Withdrawal of the rejection is respectfully requested.

### **III. Conclusion.**

In view of the remarks made herein, Applicants respectfully submit that Claims 20-23, 25, and 28-31 are in condition for allowance and request notification of same.

Respectfully submitted,

  
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